

April 20, 2012

Comments on the Draft Baseline Ecological Risk Assessment (BERA) San Jacinto River Waste Pits Superfund Site, March 2012, on behalf of the Port of Houston Authority (PHA)

On behalf of the Port of Houston Authority (PHA), HDR has reviewed the Draft Baseline Ecological Risk Assessment (BERA) for the San Jacinto River Waste Pits Superfund Site, prepared by Anchor QEA/Integral Consulting, Inc., dated March 2012, and submits the following comments:

A. Introduction

A basic tenet of CERCLA risk assessment is ensuring that the process is transparent, reasonable, and consistent with other work of similar scope. This includes providing information on the rationale, constraints, assumptions, value judgments, decisions, limitations and uncertainties inherent in the risk analysis. This review is focused on that tenet. HDR also focused attention on risk-based technical issues; overall compliance with accepted regulatory guidance; and the appropriate incorporation of underlying scientific studies. These comments do not include an in-depth review of the numerous calculations, toxicity or other values, or fact-checking.

The risk assessment should be understandable and reproducible, and use standardized procedures and terminology. The scope and objectives, data, and data sources should be described and referenced, and the data evaluated for its quality and relevance. The data inclusion/exclusion criteria and rationale should be provided. The reasoning, calculations or modeling used in the risk assessment should be explained and justified. The conclusions reached should address the basis for doing so and the uncertainties or data gaps that could influence the results and conclusions.

It is our opinion that - as presented and without clear agency endorsement of specific findings and decisions - portions of the draft Baseline Ecological Risk Assessment (BERA) for the San Jacinto River Waste Pits Superfund Site do not satisfy the requirement to be transparent, reasonable, and consistent with other work of similar scope, as will be detailed in the comments that follow. In several places, information as provided is not adequate because it does not clearly explain the rationale and assumptions used and the uncertainties inherent in the risk analysis.

Recommendations of acquiring additional information, analysis or other action to be incorporated into the final BERA, as well as the human health risk assessment (HHRA) are included where appropriate in italics, following specific comments.

B. Approach to BERA

The characterization and management of dioxin and dioxin-like PCBs is under close study and scrutiny by EPA and other stakeholders. The science is evolving in real time and as it does, the means of

determining the risk and remedial action are evolving as well. Because of the potentially critical implications of the site investigation and remediation moving forward, please note:

- USEPA published its *Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments, Volume 1 ("Reanalysis")*, on February 17, 2012. The Reanalysis document provides TCDD hazard identification and dose-response information and updated information on non-cancer health effects from TCDD exposure, including a reference dose (RfD). The dioxin cancer assessment (under development) is expected to provide cancer health effect data and risk-based values relevant to site remediation.

EPA is in the process of addressing several issues related to dioxins and dioxin-like PCB contamination. These include the comprehensive human health and exposure assessment for dioxin and a review of dioxin soil clean-up levels currently in use across the country. While this effort is focused on human health impacts, the risk management decisions (e.g., review of clean-up levels) could be applicable within the timeframe and regulatory authority for performing this remedial action, including consideration of ecological impacts.

- The EPA *Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans and Biphenyls in Ecological Risk Assessment ("Framework")* was not found in any of the lists of BERA references. Table B-7 in the BERA is a summary of TEF values; it includes World Health Organization references. The Framework provides EPA's current policy for incorporating Ecological Toxicity Equivalence Factors (ECO-TEFs) in ecological risk assessments and should be referenced and applied in this analysis.

HDR recommends that EPA direct the Responsible Parties to incorporate the Reanalysis and Framework documents in the BERA; as well as in other documents appended to the BERA and in those documents that will incorporate the BERA's conclusions.

C. Items that were to be incorporated into the BERA (including from the North Impoundment SLERA)

To better understand the basis of the draft BERA and whether issues previously identified have been addressed and to ensure that the RI/FS process can continue to produce a protective remedy, HDR reviewed comments on the PSCR, Screening Level Ecological Risk Assessment (SLERA), Data Gap Memo and several other previous documents to evaluate whether the following issues have been addressed:

1. Definition of what constitutes background: There are numerous inconsistencies and questions related to the data set, how it was chosen and used. As an example, the BERA refers to "upstream" background in a dynamic, tidal setting (Table 6-2, 6-7, 6-8); and no description of the samples that constitute background levels is provided on p. 3-28. The preparation and submittal of a Data Evaluation Report (DER), prior to the RIFS (and before the BERA and HHRA reports are finalized) may be a helpful addition to the project. A DER would provide a summary of the data set, its quality, use, samples considered background – and provide an analysis of statistical measures that would discern what the data quality objectives (DQOs) were and if they have been met.

Issues surrounding data statistics have not been fully addressed in the BERA. HDR suggests that a DER (or equivalent) be required of the Responsible Parties to clarify the robustness of the data used in the BERA, and later, those data to be incorporated in the HHRA and RI/FS. If a DER exists, it should be clearly referenced in the BERA.

2. Compliance with applicable federal and state guidance (besides BERA guidance addressed below separately) remains in question, regarding several critical, yet basic issues related to preparation of the BERA. If the Responsible Parties believe the issues below are addressed, more specific citations to the sources should be identified in the BERA:

- Calculation of exposure concentrations;
- Exposure units/sampling locations (e.g., fish collection areas);
- Consideration of temporal and spatial variations;
- Details of the unmixing analysis and resulting (described as “drastically different”) TEQs;
- Analysis of these factors in interpreting the data and need for additional sampling;
- Derivation of background concentrations;
- Choice of species and endpoints studied;
- Contamination attributed to other sources;
- Overall statistical analysis (e.g., calculation of data correlations - R and R²); and
- Choice of ARARs/TBC criteria

Of particular concern are statements that surface water quality criteria (a typical ARAR), derived to be protective of human and ecological receptors “should not override site-specific values”. It should be clarified whether or not this statement implies that site-specific values are equal to or more conservative than any ARARs. If not, this statement may be of concern considering that the site is located in a dynamic and complex environment, where adequate site-specific exposure and risk assessment is difficult, at best.

The statement that including Cedar Bayou data in the analyses “may result in unattainable remedial goals” (see HDR August 26, 2011 comments on Summary of RI/FS Data Gaps) is not consistent with the approved work plans and was not the intent of sampling Cedar Bayou (to better understand background conditions). Attainability of ARARs is considered in any Superfund remedy selection, particularly where the technical restraints of potential remedies are well-documented. However, the data should not be pre-judged or omitted from the risk analysis, but, instead should be fully considered to allow appropriate risk management decisions to be made.

HDR continues to recommend that the Responsible Parties be required to cite specific federal and state guidance in the BERA and other Site documentation, and provide the rationale and/or precedent for any variation from the norm. Moving forward into the Human Health Risk Assessment and RI/FS, compliance with or explaining any deviation from guidance becomes even more critical.

3. The level of conservatism inherent in the BERA is unclear and, likely overstated. The definition of background, statistical analyses used, and studies chosen for incorporation in the BERA are some examples of where the basis to consider this a conservative scenario may be lacking. The

idea of hill-topping, noted in previous HDR comments, is a means of compliance averaging of contaminant concentrations that is not generally accepted. Use of such “averaging” could have particularly severe effects at this Site, given the varying levels of dioxins and other contaminants known to exist. Use of “averaging” would also affect statistical testing used in remedy and cap material selection.

HDR recommends that the Responsible Parties be required to explain their rationale for the numerous decision points included in the BERA and any successive documents so that the reasoning and conclusions are transparent and understandable, and conservatism is demonstrated.

4. Numerous conclusions appear to be pre-judged in the BERA and carried through from other documents (e.g., characterization of South Impoundment data, sediment background concentrations, and presence of groundwater within the impoundments). The BERA also seems to assume facts not in evidence, i.e., eliminating pathways of exposure because they “think” they will not be as significant as some others or because they were “generally negligible” for other receptors (p. 6-21); or dismissing them outright, e.g., transport of groundwater contaminants to surface water and sediment.

The ecological and human health risks are to be measured cumulatively, as all pathways may contribute to the overall adverse effects. The choice of remedy – and inherent risk management decisions – require a full understanding of what contaminants and pathways of exposure result in excess cancer risk and/or elevated non-cancer Hazard Indices.

As above, HDR recommends that the Responsible Parties be required to explain the rationale for their assumptions and conclusions so that the reasoning and conclusions are transparent and understandable.

5. Review of the USEPA’s Draft PSCR comments, specifically as they relate to issues that could impact the BERA, reveals numerous concerns that EPA has asked the Responsible Parties to address moving forward. (See November 22, 2011 HDR memorandum and December 8, 2011 EPA letter providing comments on the July 2011 Draft PSCR.) These concerns include, but are not limited to:
 - The choice of COPCs, screening levels, and other information included in the BERA;
 - Clarification of the adequacy and quality of media-specific data sets, critical to the value of the ecological and human health evaluations;
 - An explanation of the complexities of the tidal flow regime in the estuary;
 - A complete comparison of contaminant concentrations found vs. ARARs/TBC criteria, also critical in choosing a protective remedy;
 - The appropriateness and accuracy of the statistical analyses, an understanding of which is needed as the basis for any other analyses included in the RI/FS process;
 - Inconsistencies in the temporal and spatial aspects of the data set;
 - Compliance with applicable guidance (e.g., TCEQ RG-366/TRRP-24)

Many of these concerns remain unaddressed in the BERA and can directly impact the evaluation of ecological and ultimately, human health risks. They should be addressed and revised to EPA's satisfaction prior to completing/approving the final BERA.

6. Despite EPA ecological risk guidance emphasis on the identification of ecological receptors to define food webs specific to impacted habitats, for inclusion in the SLERA/BERA, neither the SLERA nor draft BERA directly addresses the need to develop a food chain CSM or perform a risk analysis for the persistent, bioaccumulating chemicals of concerns present. There are several points in the SLERA where items that point toward a food chain model are mentioned (e.g., consumption of contaminated prey, trophic transfer being important where there are bioaccumulative COCs, see pp. 3-1-, 3-17). But there is no mention of a food chain being considered in the SLERA, BERA, or other documents reviewed.

EPA should direct the Responsible Parties to provide (or expand) its description and evaluation of food chain implications in the BERA.

7. A related issue, also noted in the South Impoundment SLERA, is that EPA guidance requires that ecological relevance, exposure potential, sensitivity, social or economic importance and availability of natural history information be evaluated to identify measurement receptors in determining food webs. The criteria indicated as being used in the BERA do not include ecological relevance or species sensitivity (see p. A-1).

Recent literature, including but not necessarily limited to, *Assessment of ecological risk from bioaccumulation of PCDD/Fs and dioxin-like PCBs in a coastal lagoon* (Micheletti, et al, 2007) describes methods available to evaluate ecological risk from dioxin-like PCBs and PCDD/Fs in organisms that are representative of the food web of a coastal area, using the EPA Guidelines for Ecological Risk Assessment. As noted in the study, statistical pattern recognition techniques (e.g., Principal Component Analysis) can help match congener patterns to profiles from point sources and help compare concentrations in tissue to Ambient Quality Criteria and literature toxicity data to estimate effects. In *Spatially distributed ecological risk for fish of a coastal food web exposed to dioxin* (2008) the same author evaluated the risk posed to edible fish species in an aquatic food web, using a kinetic bioaccumulation model. The spatial distribution of risk identified different areas and calculated dioxin exposure concentrations for sediment, water, and organisms within each area. No-effect concentrations were calculated for each fish species from literature data. Risk was estimated at 90 and 99% protection levels.

HDR recommends that the Responsible Parties be required to review the methods of these and other studies (if identified by the agencies) and provide additional information on why they chose not to complete a food chain CSM and model – beyond the brief and somewhat dismissive explanation provided on p. 6 of the Bioaccumulation Technical Memorandum - to help develop a robust analysis of the bioaccumulation effects that is not currently evident in the draft SLERA of BERA documents.

8. It is stated that the CSM will be refined in the BERA; however minimal language is provided in the BERA. The graphical representation of the CSM (Figure 1-1) does not capture the complexities of the system under study or the bioaccumulative food chain.

An expanded and refined CSM should be provided.

9. The Site is in proximity to residential development, with documented recreational use, yet only industrial use is assumed to occur.

The EPA should consider residential and recreational use.

10. The discussion of benthic macroinvertebrates and fish receptor species in the SLERA is more detailed than that in the BERA (e.g., several guilds and species are identified in the SLERA, while only one species, killifish, is mentioned in the BERA. It is noted that as a species, the killifish has developed tolerance to dioxins over long periods of exposure (p. 3-7).

EPA should require that additional fish species be evaluated for inclusion in the BERA.

11. In performing the screening level exposure estimate, only seven sediment samples from within the impoundments were used. Using these data, chemicals to be carried forward were decided, with further screening of "secondary" COPCs said to be anticipated after additional sediment sampling data are available (p. B-26, Appendix B of RI/FS, North Impoundment SLERA). HDR does not find where this has been done in the BERA.

EPA should require evaluation of additional COPCs or an evaluation of why additional COPCs are not required.

12. VOCs identified as COIs were never analyzed in sediments; therefore there is no data with which to analyze risk from these chemicals.

This should be addressed as deemed necessary in the SAP or uncertainty analysis, and reasons for requiring these data (or not) provided in the BERA.

13. Given the extent of uncertainties inherent in the BERA, starting with the use of a very limited data set, Section 4, the Uncertainty Evaluation (Chapter 7 and p. B-30) sets forth the justification of the Responsible Parties rather than a complete discussion of the uncertainty, or the resulting confidence in the results and conclusions of the SLERA.

EPA should require an expanded description of uncertainties in Chapter 7.

14. In consultation with an EPA Ecological Risk Assessor and/or BTAG, contaminants of concern may be refined, considering background contaminant concentrations, the frequency and magnitude of detection, dietary issues (e.g., essential nutrients) and the bioaccumulation potential and resulting impacts on higher trophic level species. This last is to include an evaluation of bioaccumulation, biomagnification, and bioconcentration of each contaminant. The uncertainty contributed by the refinement must be addressed.

See The Role of Screening-Level Risk Assessments and Refining Contaminants of Concern in Baseline Ecological Risk Assessments, EPA 540/F-01/014, June 2001. This document is not listed as a BERA reference. Figure 3-4 in the BERA indicates different criteria were used in the

“interpretation of fish and wildlife hazard quotients”, which then appears to have been used as a screening process for contaminants of concern.

HDR recommends these issues be reviewed to determine whether the rationale, criteria, and conclusions of the SLERA and BERA are in accordance with applicable guidance and appropriate for this Site and if they should be carried forward in the RI/FS process, including incorporation into the HHRA.

D. Draft SLERA for the South Impoundment

The draft SLERA for the South Impoundment is included as Appendix E to the draft BERA; at this time it only addresses the Phase I soil investigation results and does not incorporate results of the additional sampling required by USEPA.

15. EPA guidance requires that ecological relevance, exposure potential, sensitivity, social or economic importance, and availability of natural history information be evaluated to identify measurement receptors in determining food webs. Many of these criteria are not included in text in the draft SLERA for the South Impoundment; most notably excluding any evaluation of ecological relevance (see p. E-8, Section 2.3.1 – Selected Receptor Surrogates). The list in text also appears to conflict with the list provided in Table E-2, which includes sensitivity, where the text does not address this critical issue.

HDR recommends that the draft SLERA for the South Impoundment and other risk documents be revised to re-evaluate species and measurement endpoints based on the selection criteria from EPA guidance. For example, Table E-3 lists stable or increasing populations as assessment endpoint. Given the transitory nature of some of the bird populations, in particular, this is just one decision point that should be reviewed by EPA prior to accepting the draft BERA.

This re-evaluation, along with incorporation of the additional sampling data will necessitate reconsideration of the CSM and food chain modeling, COPC_{ES}, numerous values used in calculations, resulting risk analyses and conclusions. The validity of several statements in the draft SLERA, e.g., “since the majority of dioxin/furan concentrations are below background...the potential for transport via soil to aquatic environment is considered negligible” (p. E-6, top paragraph); “biomagnification seems limited to a small number of chemicals” (without identifying which those are, p. E-7, Section 2.2.2) should also be reconsidered.

Once completed, the revised SLERA and the impact of the revisions on the overall site risk analysis should be reviewed in further detail prior to developing the South Impoundment BERA and finalizing the BERA under review that is the subject of this memo.

E. Specific Comments on BERA and Compliance with Applicable Federal and State Regulation and Guidance

Several issues were noted regarding consistency between the BERA and applicable regulation and guidance, including:

16. Figure 1-1 is a gross simplification of the local ecosystem and potential impacts. For instance, only one arrow shows contaminants going to “biota,” yet the BERA correctly addresses many more mechanisms.

The CSM figure should be expanded and corrected.

17. Page 2-2, line 1.

What on-site sources are referred to in this statement?

18. Figure 2-2 combines the worker and trespasser categories.

Additional justification should be provided for why these categories should be combined.

19. Page 2-5 first bullet is a nonsequitor.

20. Figure 3-2 has a legend for “Reservoirs” and includes “(e.g., reservoirs)” in another category.

The figure and legend should be corrected to convey the accurate information.

21. Page 3-5 and Appendix B, with Table B-4

Ensure that these references are either standard or appropriate references that conservatively and accurately convey the state of scientific knowledge of this information.

22. Page 3-8, line 23, notes that turtles have been noted as exhibiting abnormalities, yet later in Chapters 6 and 8 this information is not addressed.

Recognition that exposure is likely to cause abnormalities must be cited and included in the BERA risk analysis.

23. Page 3-12, Section 3.4.2 claims there is no site specific information on species either on or using the Site.

This is a serious oversight to not have had an on-site assessment of species. How will EPA rectify this omission?

24. Page 3-13, line 12.

EPA and the Responsible Parties should comment on whether any migratory species require evaluation.

25. Page 3-16 notes that the alligator snapping turtle is on the state list.

The alligator snapping turtle’s life history and occurrence should be discussed, as the other T&E species are, in the following paragraphs.

26. It is stated in the BERA that T&E species will not be represented by surrogate species, “as this is conservative and could result in an overestimate of risk to these species” (p. B-19). EPA guidance indicates that when conducting an ecological risk assessment, the USFWS or state Natural Heritage program should be contacted to determine if these species are or might be present. Once the presence of a special-status species is confirmed or considered likely, information on the species, *as well as for surrogates* should be included. While there is often more information available for T&E species, the use of surrogate species usually is necessary when an assessment endpoint is a T&E species.

Documentation of consultation with the USFWS or the state National Heritage program and consideration of their recommendations should be provided.

27. The criteria used to choose surrogate species are not consistent with EPA guidance (p. 3-17).

Selection of surrogate species in accordance with EPA guidance should be documented.

28. Selected receptor surrogate species exclude amphibians (p. 3-18); these are not included in the BERA. The alligator snapping turtle was chosen as the surrogate species, based only on the fact that natural history information was available for this species (p. B-13). Birds of prey (raptors) are also dismissed. See Table 3-9.

The rationale and validity should be examined before accepting these decisions.

29. Page 3-19, lines 20-25. While no data regarding population level effects exists, an objective scientific commentary on the sensitivity of the species present compared to population impacts should be provided.

The BERA should indicate whether a population might be susceptible to marked declines or what species are particularly sensitive to contaminants present.

30. Page 3-20, Field collections should have noted any abnormalities in species.

Field observation, particularly those documenting potential effects of Chemicals of Interest (COIs) should be noted in the BERA.

31. Respiration of Chemicals of Interest (COIs) is stated to be considered implicitly through use of sediment screening values; and that respiration by fish is potentially significant and will be addressed in the BERA (p. B-22). However, we question the use of sediment criteria in evaluating inhalation risk. Also, the BERA does not address this pathway, and risks to fish overall are said to be negligible.

This pathway should be considered in the BERA and the criteria used and rationale for inclusion/exclusion clarified.

32. Species noted within the area and measurement endpoint selection criteria should be consistent with EPA risk guidance. Table 3-10 lists stable or increasing populations as an assessment endpoint.

Given the transitory nature of some of the bird populations, non-reproductive effects, and other issues (e.g., in the TRV endpoints in Table 5-3), these decision points should be reviewed to determine if they are appropriate.

33. Page 3-24, Table 3-12 notes that no range is available for the Neotropic Cormorant.

What range was used and how was the range used in the risk calculations?

34. Page 3-26, line 14 defines “negligible” to be conditions where no HQ exceeds 1, yet later in the BERA the term “negligible” is used dozens of times with other implications.

The BERA should be edited to use the term “negligible” only with a specific definition; other terms should be defined and used where that definition does not apply.

35. The rationale and criteria used in developing and/or choosing Toxicity Reference Values (TRVs) and other values should be transparent and be consistent with regulatory guidance, specifically as it relates to the documents discussed in the Introduction of this memo. Tables B-6 through B-16 include a variety of TRV values for egg mortality, mammals, etc. with a variety of comments whose derivation, accuracy and/or relevance is not explained or referenced.

Comments on uses of the data should be added to Tables and text as needed to be consistent with guidance.

36. Page 4-8, line 16 discusses hard head catfish.

Why were no Site area data available for this species?

37. Figure 4-9.

Why is there no killdeer habitat mapped to the south of I-10?

38. Figures 4-9, 4-10, 4-11, 4-12 do not clearly show the boundaries of habitats because the boundary lines stop part way around areas.

The figures need to have clarified boundaries and legends.

39. Page 4-10, line 6.

Should include consistent units for range, e.g., 36 m to 0.15 km² (450 m).

40. Page 4-10 lines 1-12 discuss data where killifish were found.

Are there other habitats that, with remediation, might support a population of killifish? The BERA should evaluate the suitability of habitat.

41. Table 4-6 illustrates the effects of data manipulation in that the net effect of where exposures are assumed and how they are calculated leads to RME values at or only slightly higher than Central Tendency (CT) exposures in most cases. Many objective BERAs have RME exposures two to ten times higher than CT exposures.

EPA should critically review how the data in the BERA were managed to arrive at such small increases from CT to RME exposures and ensure that such interpretations follow Agency guidance.

42. Table 4-6 refers to RME, a term not defined in the acronyms.

This term should be defined accurately, presumably as RME, see above.

43. Page 4-24, second paragraph states that polygons were edited to line features after being “clipped appropriately”.

What criteria were used to clip the polygons and how is “appropriate” defined for purposes of using these data in the BERA?

44. A number of the values incorporated into BERA analysis appear to be based on one study (e.g., Nosek, et al, 1992b, p. 4-15). In checking the studies cited, it became evident that while some were standard references accepted by the scientific community, others were less robust, with no clear rationale or criteria provided for their use.

EPA should confirm the applicability of the Nosek study, and other studies cited in the Draft BERA.

45. There is a lack of transparency in choices made, exceptions to guidance, etc. For example, the data presented in numerous tables (e.g., Tables 4-3 through 4-19) lack references, data sources, underlying calculations and/or explanations for what was considered in using best professional judgment, making it almost impossible to check compliance with EPA risk guidance or derivation and accuracy of the information being presented, which is very complex and used to assess ecological risks.

EPA should require clarification where it deems appropriate.

46. Address the definition and application of the concepts of “background” and “post-TCRA” in terms of risk and how these will be incorporated moving forward in the remedial process. As noted, this is largely related to concerns with the data set being used.

The data rules and data sets used in the BERA should be reviewed and potentially re-evaluated by the regulatory agencies. The risks associated with the baseline condition and post-TCRA should be clearly stated.

47. Page 6-2, line 12 refers to “up to 25,000 ng/kg,” yet the absence of reliable data is later discussed.

If this citation remains in the document, (both here and in Chapter 8) it should state "ranges from 2 to 25,000 ng/kg," as the appendix data table shows.

48. Page 6-4 notes possible bias of phenol data.

This issue should be discussed when the OC calculation is originally cited earlier in the BERA.

49. Chapter 6 has numerous citations to "negligible risks."

This can be a subjective term that deserves a basis for use, as noted earlier.

50. Page 6-17, line 22 uses the term "greater than known."

This term should be replaced with "greater than expected."

51. Chapters 7 and 8 (Uncertainty and Conclusions)

It should be noted that the BERA does not address any additive effects of COPCs. The significance of 8% and greater expected effects should not be minimized because they may be critical to a species population's survival and an overall functioning ecosystem.

52. Page 6-6, line 27 refers to the Reference Envelope Value (REV) for aluminum. The REV cited is 13,300 mg/kg, or 1.33 % aluminum.

Comment or qualification for this REV should be offered. Such an astounding concentration should not be accepted silently by the Responsible Parties or EPA, but should be acknowledged as an extraordinary background estimate. The application of a REV approach has numerous constraints related to high variance in the data, presence of hot spots, evaluation of statistical "detectable differences" and the actual number of reference, or background site sample locations. These should be reviewed and considered in accepting such a high background value.

F. Validity of BERA's conclusions

53. Conclusions are drawn without having had the benefit of agency review of draft SLERA for the South Impoundments (included in BERA as Appendix E). Adverse effects may be cumulative and cannot be fully assessed without knowing conditions related to the South Impoundments, including the most recent sampling and analytical results and the assumptions and uncertainties inherent in and the overall results of the risk analysis. For example, while the source areas may be distinct, each source areas relationship to habitat and exposure areas, and potentially species and endpoints of concern for inclusions in the BERA, may overlap.
54. Conclusions are made that risks are negligible. In several cases, these conclusions appear to be based on what may be faulty assumptions, and/or evaluation and decision processes that do not conform to applicable regulation and guidance (pp. 4-19, 4-30; 6-4 through 6-9).
55. This review does not include a check of the accuracy of the exposure point concentrations provided in Tables C-1 through C-3. However, there are serious questions regarding the data set

used for the BERA, which is the basis for these exposure concentrations. There are also concerns regarding both the data and methods used in the Estimation of Dioxin and Furan Concentrations in Terrestrial Invertebrate Tissue for the Exposure Model, included in Appendix D. One particular concern is that the data set used is said to be from another Superfund site; yet no method references are provided.

The BERA should cite appropriate references and methods.

56. An overarching concern is the lack of an explanation of the rationale and/or criteria used for choosing studies, and the ecological criteria or other values derived from such studies. While Appendix B (Ecotoxicity Profiles) lists acceptability criteria (see p. B-9), other selection criteria modifying, and potentially confounding those criteria, are provided in the bullets on p. A-3 of the BERA. Text describing the basis for exposure assumptions used in modeling and the receptor profiles (p. A-3) also lacks clarity in explaining the choices made.

As an example of study evaluation criteria, EPA, in deriving its national ecological soil screening levels (Eco-SSLs) used nine criteria to numerically score each reported study. Each study had to receive a total score greater than ten to be considered for use. The documentation for Eco-SSL scoring noted that the choice should be objective, with professional judgment used as needed. See *Eco-SSL Standard Operating Procedure (SOP) #2: Plant and Soil Invertebrate Literature Evaluation, Data Extraction, and Eco-SSL Calculation*, OSWER Directive 92857-55. Given the critical role that these criteria play in the BERA and ultimately, the choice of remedy, this lack of transparency is a major deficiency.

The studies used in preparing the BERA should be evaluated in accordance with one specific set of criteria and a rationale acceptable to EPA, to allow for an independent review of the supporting work and reasons for their being chosen.

G. Development of Fish Tissue Analysis and How it may Impact the Human Health Risk Assessment Moving Forward

A complete understanding of how data was collected and analyses completed for the BERA, can lay much of the groundwork for the HHRA, particularly for the evaluation of fish ingestion pathways of human exposure. There are several references that may prove helpful in integrating the ecological and human health risk assessments, including:

- Framework for the Integration of Health and Ecological Risk by Glenn Suter, et al, at http://whqlibdoc.who.int/hq/2001/a76785_framework.pdf describes how integrated risk assessment can be used to improve the quality and efficiency of assessments through the exchange of information between human health and environmental risk assessors and provide more holistic inputs to the remedial decision-making process. Suter defines integrated risk assessment as a science-based approach that combines the processes of risk estimation for humans, biota, and natural resources in one study. Integration involves all phases of analysis, from planning through decision making.

- The ability to make appropriate remedial decisions may be limited by incomplete or incoherent information provided by risk analyses overly limited in scope; i.e., risk analyses to human health; that do not consider nonhuman organisms, populations, and ecosystems. Advantages to integrated risk analysis include:
 - Providing coherent results and a strong basis for action to support decision making, considering the spatial and temporal scales, level of conservatism, assumptions, and uncertainty.
 - Ecological and human health risks are interdependent - humans depend on nature for food, water and other things diminished by the effects of toxic chemicals. Ecological impacts may result in increased human exposure to contaminants. Integrating health and ecological risks can better incorporate important modes of action that involve interactions between ecological and human health effects.
 - Because nonhuman organisms often are more heavily exposed to environmental contaminants and may be more sensitive, they can serve as sentinels for potential effects on humans. By identifying impacts to species at the higher trophic levels (e.g., fish-eating birds), we can better predict possible impacts to people.
- Fish bioaccumulation and biomarkers in environmental risk assessment: a review, Ron van der Oost et al, available at <http://jllakes.org/web/Fish-bioaccumulation-biomarker-ETP2003.pdf> discusses the difficulties and alternate means to accurately predict bioaccumulation in fish. The article notes that even though the most promising fish bioaccumulation markers are body burdens of persistent organic pollutants, e.g., PCBs, the fact that PCDD and PCDF levels in fish tissues are very low as compared with the sediment levels, may limit their value as bioaccumulation markers. This is one example of the scholarly research that should be considered as the BERA analyses move into the HHRA.
- In March of this year, a paper entitled *Reasoning behind 2000 TSWQS adoption of fish tissue-based criteria* discusses the TCEQ adoption of human-health criteria for fish tissue for PCBs, dioxins/furans, and DDT, which were approved by EPA.

Fish-tissue criteria for other bioaccumulative chemicals are proposed, to allow site-specific flexibility (particularly for bioaccumulation factors) in calculating allowable water-column concentrations for wastewater permitting and other regulatory actions. These actions should be considered in finalizing the BERA and completing the HHRA.

- Planning and implementation of fish and other food chain sample collection should also consider the methods, procedures and protocols of the EPA's *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories. Volume I: Fish Sampling and Analysis, Third Edition* (2000) and the publicly available data from the Environmental Monitoring and Assessment Program (EMAP) sampling results for Gulf Coast estuaries.

- For the Gowanus Canal NPL Site RI/FS, exposure point concentrations (EPCs) were calculated for each medium (e.g., sediment and fish tissue) and data groupings for PCB congeners were analyzed for “dioxin-like” PCB TEQ concentrations, “non-dioxin-like” total PCB concentrations, and total PCB concentrations, in accordance with EPA’s 1996 PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures. EPA/600/P-96/001F. A data quality evaluation and explanation of the associated uncertainties were included. TEQ concentrations for “dioxin-like” PCBs were calculated using World Health Organization (WHO) toxicity equivalency factors (TEFs).

Additional references to consider in the fish tissue analysis and determining PCB/TCDD health risks for the HHRA include:

- USEPA, 1995. Health Assessment Document for Polychlorinated Dibenzo-p-Dioxins. Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office. Cincinnati, OH. EPA 600/8-84-014F.
- USEPA, 1997. Exposure Factors Handbook. EPA/ 600/P-95/Fa, -Fb, and -Fc.
- USEPA, 2000. Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories. Volume 2: Risk Assessment and Fish Consumption Limits - Third Edition. Appendix C. Dose Modifications Due to Food Preparation and Cooking. EPA 823-B-00-008. November.
- USEPA Region 3, 2010. Regional Screening Level Fish Ingestion Table November 2010. Available at <http://www.epa.gov/reg3hwmd/risk/human/index.htm>. December.
- USEPA, 2010. Recommended Toxicity Equivalence Factors (TEFs) for Human Health Risk Assessments of 2,3,7,8-Tetrachlorodibenzo-p-dioxin and Dioxin-Like Compounds. Risk Assessment Forum, Washington, DC. EPA/100/R-10/005.
- New Jersey Department of Environmental Protection, 2002. Estimate of Cancer Risk to Consumers of Crabs Caught in the Area of the Diamond Alkali Site and Other Areas of the Newark Bay Complex from 2,3,7,8-TCDD and 2,3,7,8-TCDD Equivalents. Available at <http://www.state.nj.us/dep/dsr/craboutreach/crabsra.pdf>.

The characterization and management of dioxin and dioxin-like PCBs is evolving, and there are potentially critical implications for the San Jacinto River Waste Pits investigation and remediation moving forward. The *Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments* provides TCDD hazard identification and dose-response information on non-cancer health effects from TCDD, including a reference dose (RfD).

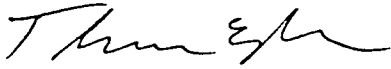
The dioxin cancer assessment is expected to provide cancer health effect data and risk-based values relevant to site remediation, at lower concentrations than those for non-cancer effects. This may result in lower dioxin clean-up levels.

In addition, the *Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans and Biphenyls in Ecological Risk Assessment* was not found in the BERA references and should be considered in finalizing this evaluation.

HDR recommends that these references be considered in regulatory review and acceptance of the draft BERA and other documents appended to the BERA or that will incorporate the BERA’s conclusions.

Any questions concerning these comments should be communicated to Linda Henry, Port of Houston Authority.

Sincerely,

Handwritten signature of Thomas E. Pease in black ink.

Thomas E. Pease, PE, PhD
Senior Professional Associate

Handwritten signature of Lisa K. Voyce in black ink.

Lisa K. Voyce
Toxicologist/Risk Assessor

cc: Neil McLellan, PE